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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 05-959-B5; EX03-077C-US)

In the Application of: )  
Gregory D. Plowman et al. )  
Serial No.: 10/532,405 ) Art Unit: 1645  
Filed: May 18, 2006 ) Examiner: Unassigned  
For: CDKL1 as Modifier of Branching ) Confirmation No. 5781  
Morphogenesis and Methods of Use )

TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In regard to the above identified application,

1. We are transmitting herewith the attached:
  - a) Information Disclosure Statement (3 Sheets);
  - b) Forms PTO/SB/08a and SB/08b (4 Sheets);
  - c) Copies of Cited References; and
  - d) Return receipt postcard.
2. With respect to fees:
  - a) No fee is believed to be due at this time.
  - b) Please charge any underpayment or credit any overpayment our Deposit Account, No. 13-2490.

3. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1, are being deposited via First Class Mail with the United States Postal Service, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on Nov. 28 2006.

Respectfully submitted,

Date: Nov. 28. 2006

Sherri L. Oslick  
Sherri L. Oslick, Ph.D.  
Reg. No. 52,087



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 05-959-B5; EX03-077C-US)

Application of: )  
Gregory D. Plowman et al. )  
Serial No.: 10/532,405 ) Art Unit: 1645  
Filed: May 18, 2006 ) Examiner: Unassigned  
For: CDKL1 as Modifier of Branching ) Confirmation No. 5781  
Morphogenesis and Methods of Use )

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449. This Information Disclosure Statement is being submitted prior to the issuance of the first Office Action. As such, no fee is due.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative relevance between references, whether cited in this or prior statements. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

Foreign Documents

1. PCT Patent Publication No. WO 02/059620, published August 1, 2002 (BIANCO et al.).
2. PCT Patent Publication No. WO 02/077033, published October 3, 2002 (McKENZIE et al.).

## Other Documents

3. RADVANYI et al, "Pancreatic beta cells cultured from individual preneoplastic foci in a multistage tumorigenesis pathway: a potentially general technique for isolating physiologically representative cell lines," *Molecular and Cellular Biology*, July 1993, Vol. 13, pages 4223-4232.
4. SLOMAN et al., "The EGF-CFC family: novel epidermal growth factor-related proteins in development and cancer," *Endocrine-Related Cancer*. December 2000, Vol. 7, pages 199-226.).
5. ADAMSON et al., "Cripto: a tumor growth factor and more," *Journal of Cellular Physiology*, March 2002, Vol. 190, pages 267-278.
6. ATABEY et al., "Potent blockade of hepatocyte growth factor-stimulated cell motility, matrix invasion and branching morphogenesis by antagonist of Grb2 Src homology 2 domain interactions.
7. BARROS et al., "Differential tubulogenic and branching morphogenetic activities of growth factors: implications of epithelial tissue development," *Proceeding of the National Academy of Sciences of the United States*, May 9, 1995, Vol. 92, pages 4412-4416.
8. Database Medline on STN, ACS (Columbus, OH, USA), Accession No. 1999265734, LALANI et al, "Trefoil factor-2 human spasmolytic polypeptide, promotes branching morphogenesis in MCF-7 cells," *Laboratory Investigations*, May 1999, Vol. 79, pages 537-546.
9. KOCHEKPOUR et al., " The von-Hippel-Lindau tumor suppressor gene inhibits hepatocyte growth factor/scatter, factor-induced invasion and branching morphogenesis in renal carcinoma cells," *Molecular and Cellular Biology*, September 1999, Vol. 19, pages 5902-5912.
10. PISCIONE et al., "BMP-2 and OP-1 exert direct and opposite effects on renal branching morphogenesis," *American Journal of Physiology*, December 1997, Vol. 273, No. 6, part 2, pages F961-F975.
11. PETERS et al., "Targeted expression of a dominant negative FGF receptor blocks branching morphogenesis and epithelial differentiation of the mouse lung," *EMBO Journal*, July 15, 1994, Vol. 13, pages 3296-3301.
12. Database Scisearch on STN, ACS (Columbus, OH, USA), Accession No. 1994-497414, SERRA et al., "TGF-beta inhibits branching morphogenesis and N-myc expression in lung bud organ-cultures," *Development*, August 1994, Vol. 120, pages 2153-2161.
13. SCHUGER et al., "Amphiregulin in lung branching morphogenesis: interaction with heparan sulfate proteoglycan modulates cell proliferation," *Development*, June 1996, Vol. 122, pages 1759-1767.
14. CANCILLIA et al., "Regulation of prostate branching morphogenesis by activin A and follistatin," *Developmental Biology*, September 1, 2001, Vol. 237, pages 145-158.
15. MARKER et al., "Fucosyltransferase and H-type complex carbohydrates modulate epithelial cell proliferation during prostatic branching morphogenesis," *Developmental Biology*, May 1, 2001, Vol. 233, pages 95-108.

In accordance with MPEP Sections 609 and 707.05(b), it is requested the document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Respectfully submitted,

Date: Nov. 28, 2004

By:

Sherri L. Oslick

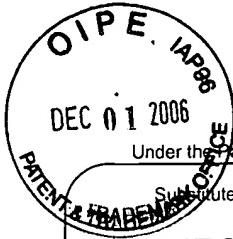
Sherri L. Oslick, Ph.D.

Registration No. 52,087

**McDonnell, Boehnen Hulbert & Berghoff**

300 South Wacker Drive

Chicago, IL 60606



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PTO/SB/08a (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

Substitute for form 1449A/PTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Shee

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**Complete if Known**

|                        |                    |
|------------------------|--------------------|
| Application Number     | 10/532,405         |
| Filing Date            | May 18, 2006       |
| First Named Inventor   | Gregory D. Plowman |
| Art Unit               | 1645               |
| Examiner Name          | N/A                |
| Attorney Docket Number | 05-959-B5          |

20

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## **U. S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|---|--------------------------------|--|---|----------------|
|                    |                       | Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known) |                                |  |   |                |
| A1                 | WO 02/059620          |   | 08/01/2002                     | BIANCO et al.                                      |   |                |
| A2                 | WO 02/077033          |   | 10/03/2002                     | McKenzie et al.                                    |   |                |
|                    |                       |   |                                |  |   |                |
|                    |                       |   |                                |  |   |                |
|                    |                       |   |                                |  |   |                |

Examiner Signature \_\_\_\_\_ Date Considered \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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[www.FormsWorkflow.com](http://www.FormsWorkflow.com)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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|                        |                    | <b>Complete if Known</b> |  |
|------------------------|--------------------|--------------------------|--|
| Application Number     | 10/532,405         |                          |  |
| Filing Date            | May 18, 2006       |                          |  |
| First Named Inventor   | Gregory D. Plowman |                          |  |
| Art Unit               | 1645               |                          |  |
| Examiner Name          | N/A                |                          |  |
| Attorney Docket Number |                    | 05-959-B5                |  |

| <b>NON PATENT LITERATURE DOCUMENTS</b> |                       |   |  |                |
|--|-----------------------|---|--|----------------|
| Examiner Initials*                     | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                           |  | T <sup>2</sup> |
|  | A3                    | RADVANYI et al., "Pancreatic beta cells cultured from individual preneoplastic foci in a multistage tumorigenesis pathway: a potentially general technique for isolating physiologically representative cell lines," Molecular and Cellular Biology, July 1993, Vol. 13, pages 4223-4232. |  |                |
|  | A4                    | SLOMAN et al., "The EGF-CFC family: novel epidermal growth factor-related proteins in development and cancer," Endocrine-Related Cancer. December 2000, Vol. 7, pages 199-226.)   |  |                |
|  | A5                    | ADAMSON et al., "Cripto: a tumor growth factor and more," Journal of Cellular Physiology, March 2002, Vol. 190, pages 267-278.  |  |                |
|  | A6                    | ATABEY et al., "Potent blockade of hepatocyte growth factor-stimulated cell motility, matrix invasion and branching morphogenesis by antagonist of Grb2 Src homology 2 domain interactions.   |  |                |
|  | A7                    | BARROS et al., "Differential tubulogenic and branching morphogenetic activities of growth factors: implications of epithelial tissue development," Proceeding of the National Academy of Sciences of the United States, May 9, 1995, Vol. 92, pages 4412-4416.                            |  |                |
|  | A8                    | LALANI et al, "Trefoil factor-2 human spasmolytic polypeptide, promotes branching morphogenesis in MCF-7 cells," Laboratory Investigations, May 1999, Vol. 79, pages 537-546.   |  |                |
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|  | A10                   | Database Biosis on STN, ACS (Columbus, OH, USA), Accession No. 1998:101625, PISCIONE et al., "BMP-2 and OP-1 exert direct and opposite effects on renal branching morphogenesis," American Journal of Physiology, December 1997, Vol. 273, No. 6, part 2, pages F961-F975.                |  |                |
|  | A11                   | PETERS et al., "Targeted expression of a dominant negative FGF receptor blocks branching morphogenesis and epithelial differentiation of the mouse lung," EMBO Journal, July 15, 1994, Vol. 13, pages 3296-3301.  |  |                |
|  | A12                   | SERRA et al., "TGF-beta inhibits branching morphogenesis and N-myc expression in lung bud organ-cultures," Development, August 1994, Vol. 120, pages 2153-2161.   |  |                |

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|-----|---|--|
| A13 | SCHUGER et al., "Amphiregulin in lung branching morphogenesis: interaction with heparan sulfate proteoglycan modulates cell proliferation," Development, June 1996, Vol. 122, pages 1759-1767.                    |  |
| A14 | CANCILLIA et al., "Regulation of prostate branching morphogenesis by activin A and follistatin," Developmental Biology, September 1, 2001, Vol. 237, pages 145-158.   |  |
| A15 | MARKER et al., "Fucosyltransferase and H-type complex carbohydrates modulate epithelial cell proliferation during prostatic branching morphogenesis," Developmental Biology, May 1, 2001, Vol. 233, pages 95-108. |  |

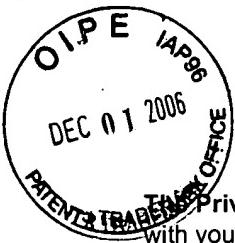
|                       |                    |
|-----------------------|--------------------|
| Examiner<br>Signature | Date<br>Considered |
|-----------------------|--------------------|

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*



## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.